K003760 MAR - 6 2001

510(k) Summary Statement
For the Lyra™ G Surgical Laser System & Accessories

General Information

A. Trade Name
Lyra G™ Series Surgical Laser System (SL Series Q-Switched Nd:YAG configuration)

B. Common Name
Laser Instrument, Surgical, Powered

C. Establishment Registration Number

2937094

D. Manufacturer's Identification

Laserscope
3070 Orchard Drive
San Jose, CA 95134-2011
(408) 943-0636
(503) 961-1688 FAX

Official Correspondent
Paul Hardiman
Manager, Regulatory Affairs/Clinical Affairs

E. Device Classification

The Lyra G Series Surgical Laser System has been specifically classified as a Class II medical device by the OB/GYN, General Plastic Surgery, and ENT Device Advisory Panels.

F. Performance Standards

The Lyra G Series Surgical Laser System conforms with federal regulations and the performance standards 21 CFR 1040.10 and 1040.11 for medical laser systems.

G. Predicate Devices:

- 800 Series Surgical Laser System and Accessories
- Aura "DL" Series Surgical Laser Systems (KTP/532, KTP/YAG™ and ND:YAG/1064 Configurations)
- Laserscope Lyra Laser System and Accessories

- Modified Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Devices with Accessories

H. Product Description:

The Laserscope Lyra G Surgical Laser System, Accessories, and Cooling Device is comprised of the following main components:

- A Laser Console
- A Fiber Port (for Delivery Devices)
- Control and Display Panels
- Operating Software
- Footswitch and Handswitch Delivery Controls
- A variety of Delivery Devices and Accessories
- A Cooling Sub-system

I. Indications For Use:

The Lyra G Series Surgical Laser System and Accessories are intended for the surgical incision/excision, vaporization, ablation and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

KTP/532 Applications

Dermatology: Photocoagualtion of cutaneous lesions including but not limited to the following general categories of lesions: Vascular lesions (Angiomas, Hemangiomas, Telangiectasia); Benign pigmented lesions (Nevi, Lentigines, Chloasma, Café-au-lait, Tattoos (including but not limited to blue and black dark tattoo ink); Verrucae; Skin Tags; Keratoses; Plaques; Cutaneous Lesion Treatment (Hemostasis, Color Lightening, Blanching, Flattening, Reduction of lesion size).

General Surgery: Vaporizing, Coagulating, Incising, Excising, Debulking, and Ablating of Soft tissue as well as in Endoscopic (e.g. laparoscopic) or open surgeries.

Gastroenterology: Tissue ablation and hemostasis in the gastrointestinal tract; Esophageal neoplastic obstructions, including squamous cell carcinoma and adenocarcinoma; Gastrointestinal hemostasis (including Varices, Espohagitis, Esophageal Ulcer, Mallory-Weiss tear, Gastric Ulcer, Angiodysplasia, Stomal Ulcers, Non-bleeding Ulcers, Gastric erosions); Gastrointestinal Tissue ablation (Benign and Malignant neoplasm, Angiodysplasia, Polyps, Ulcer, Colitis, Hemorrhoids).

Gynecology: Vaporizing, incising, or coagulating tissue associated with treatments of conditions such as: Endometriosis; Cervical, vulvar, and vaginal intraepitheal neoplasia; Condyloma Acuminata; Uterine Spetum; Intrauterine adhesions; Submucosal fibroids.

Head and Neck/Otorhinolaryngology (ENT): Tissue incision, excision, ablation, and vessel hemostasis.

Neurosurgery: Incising, excising, coagulating, and vaporizing neurological tumors of the firm textured type.

Opthamology: Post-vitrectomy endophotocoagulation of the retina.

Plastic Surgery: Vaporizing, Coagulating, Incising, Excising, debulking, and ablating of soft tissue in endoscopic and open procedures.

Spinal Surgery: Percutaneous lumbar diskectomy.

Thoracic Surgery: Vaporizing, Coagulating, Incising, Excising, Debulking, and ablating of soft tissue, including lung tissue in thoroscopic or open procedures.

Urology: Cutting, coagulating, or vaporizing urologic soft tissues.

ND:YAG/1064 Applications

Dermatology: Photocoagulation of pigmented and vascular lesions to reduce lesion size. For patients with lesions that would potentially benefit from aggressive treatment. For patients with lesions that have not responded to other laser treatments; and, for the lightening and removal of unwanted body hair in Fitzpatrick Skin Types I to VI using 1064nm, Nd:YAG.

Endoscopic/Laparoscopic General Surgery: Cutting, ablation, and/or hemostasis of soft tissue in endoscopic or laparoscopic general surgery applications, including but not limited to: Cholecystectomy, Appendectomy, Vagotomy, Pyloromyotomy.

Gastroenterology: Tissue ablation and hemostasis in the gastrointestinal tract; Esophageal neoplastic obstructions including Squamous cell carcinoma and Adenocarcinoma; Gastrointestinal hemostasis including: Varices, Espohagitis, Esophageal Ulcer, Mallory-Weiss tear, Gastric Ulcer, Angiodysplasia, Stomal ulcers, non-bleeding ulcers, Gastric erosions; Gastrointestinal tissue ablation including: Benign and malignant neoplasm; Angiodysplasia; Polyps; Ulcer; Colitis; Hemorrhoids.

General Surgery: Soft tissue general surgery applications: Skin incision; Tissue dissection; Excision of external tumors and lesions; complete or partial resection of internal organs, tumors, lesions; Tissue ablation; Vessel Coagulation.

Gynecology: Treatment of menorrhagia by photocoagulation of the endometrial lining of the uterus; Ablation of endometrial implants and/or peritoneal adhesions; Soft tissue excisional procedures, such as excisional conization of the cervix; intra-uterine gynecologic procedures where cutting, ablation and/or vessel coagulation may be indicated including Submucous fibroids, Benign endometrial polyps, Uterine septum.

Head and Neck/Otorhinolaryngology (ENT): Tissue incision, excision, ablation, and vessel hemostasis.

Hemostasis during Surgery: Adjunctive coagulation and hemostasis (bleeding control) during surgery in endoscopic (e.g. laparoscopic) and open procedures.

Neurosurgery: Hemostasis for: Pituitary Tumor; Meningioma; Hemagioblastoma; AVMs; Glioma; Glioblastoma; Astrocytoma; Oligodendroglioma.

Oculoplastics: Incision, Excision, Vaporization and/or coagulation of tissues in Oculoplastic procedures such as: Operations on the lacrimal system; Operation on the eyelids; Removal of biopsy or orbital tumors; Enucleation on eyeball; Exteneration of orbital contents.

Orthopedics: Cutting, ablation, and/or hemostasis of intra-articular tissue in Orthopedic surgical and arthroscopic applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 2001

Mr. Paul H. Hardiman
Manager, Regulatory Affairs
Laserscope
3052 Orchard Drive
San Jose, California 95134

Re: K003765
Trade Name: Lyra G Series Surgical Laser System and Accessories
Regulatory Class: II
Product Code: GEX
Dated: December 5, 2000
Received: December 6, 2000

Dear Mr. Hardiman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K003765

Device Name: LYRA G SERIES SURGICAL LASER SYSTEM & Accessories

Indications for Use:

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KTP/532 Applications

Dermatology: Photocoagualtion of cutaneous lesions including but not limited to the following general categories of lesions: Vascular lesions (Angiomas, Hemangiomas, Telangiectasia); Benign pigmented lesions (Nevi, Lentigines, Chloasma, Café-au-lait, Tattoos (including but not limited to blue and black dark tattoo ink); Verrucae; Skin Tags; Keratoses; Plaques; Cutaneous Lesion Treatment (Hemostasis, Color Lightening, Blanching, Flattening, Reduction of lesion size).

General Surgery: Vaporizing, Coagulating, Incising, Excising, Debulking, and Ablating of Soft tissue as well as in Endoscopic (e.g. laparoscopic) or open surgeries.

Gastroenterology: Tissue ablation and hemostasis in the gastrointestinal tract; Esophageal neoplastic obstructions, including squamous cell carcinoma and adenocarcinoma; Gastrointestinal hemostasis (including Varices, Espohagitis, Esophageal Ulcer, Mallory-Weiss tear, Gastric Ulcer, Angiodysplasia, Stomal Ulcers, Non-bleeding Ulcers, Gastric erosions); Gastrointestinal Tissue ablation (Benign and Malignant neoplasm, Angiodysplasia, Polyps, Ulcer, Colitis, Hemorrhoids).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ or Over –The-Counter-Use

(per 21 CFR 801.109)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003765

INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Name: LYRA G SERIES SURGICAL LASER SYSTEM & Accessories

Gynecology: Vaporizing, incising, or coagulating tissue associated with treatments of conditions such as: Endometriosis; Cervical, vulvar, and vaginal intraepitheal neoplasia; Condyloma Acuminata; Uterine Spetum; Intrauterine adhesions; Submucosal fibroids.

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Plastic Surgery: Vaporizing, Coagulating, Incising, Excising, debulking, and ablating of soft tissue in endoscopic and open procedures.

Spinal Surgery: Percutaneous lumbar diskectomy.

Thoracic Surgery: Vaporizing, Coagulating, Incising, Excising, Debulking, and ablating of soft tissue, including lung tissue in thoroscopic or open procedures.

Urology: Cutting, coagulating, or vaporizing urologic soft tissues.

ND:YAG/1064 Applications

Dermatology: Photocoagulation of pigmented and vascular lesions to reduce lesion size. For patients with lesions that would potentially benefit from aggressive treatment. For patients with lesions that have not responded to other laser treatments; and, for the lightening and removal of unwanted body hair in Fitzpatrick Skin Types I to VI using 1064nm, Nd:YAG.

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(per 21 CFR 801.109) Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Name: LYRA G SERIES SURGICAL LASER SYSTEM & Accessories

Endoscopic/Laparoscopic General Surgery: Cutting, ablation, and/or hemostasis of soft tissue in endoscopic or laparoscopic general surgery applications, including but not limited to: Cholecystectomy, Appendectomy, Vagotomy, Pyloromyotomy.

Gastroenterology: Tissue ablation and hemostasis in the gastrointestinal tract; Esophageal neoplastic obstructions including Squamous cell carcinoma and Adenocarcinoma; Gastrointestinal hemostasis including: Varices, Espohagitis, Esophageal Ulcer, Mallory-Weiss tear, Gastric Ulcer, Angiodysplasia, Stomal ulcers, non-bleeding ulcers, Gastric erosions; Gastrointestinal tissue ablation including: Benign and malignant neoplasm; Angiodysplasia; Polyps; Ulcer; Colitis; Hemorrhoids.

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Oculoplastics: Incision, Excision, Vaporization and/or coagulation of tissues in Oculoplastic procedures such as: Operations on the lacrimal system; Operation on the eyelids; Removal of biopsy or orbital tumors; Enucleation on eyeball; Exteneration of orbital contents.

Orthopedics: Cutting, ablation, and/or hemostasis of intra-articular tissue in Orthopedic surgical and arthroscopic applications.

Plastic Surgery: Cutting (incision/excision), coagulating, and vaporizing of soft tissue.

Pulmonary Surgery: Palliative treatment of benign and malignant pulmonary airway obstructions, including: Squamous Cell Carcinoma; Adenocarcinoma; Carcinoid; Benign Tumors; Granulomas; Benign Strictures.

Thoracic Surgery: Cutting (incision/excision), coagulating, and vaporizing of soft tissue. Thoracic applications including, but not limited to: Isolation of vessels for endarterectomy and/or by-pass grafts; Wedge Resections ; Thoractomy; Formation of Pacemaker pockets. Vaporization, coagulation, incision/excision, debulking, and ablation of lung tissue (Thoracoscopy).

Urology: All applications including: Superficial urinary bladder tumors; Invasive bladder carcinoma; Urethral Strictures; Lesions of the external genitalia (including condyloma acuminata).

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